Master Manufacturing Protocol Checklist

The Master Manufacturing Protocol is a written document that describes how to make a cannabis product. It lists the type and amount of each ingredient to use and each step that must be followed to safely and consistently produce the product. This protocol helps reduce adulteration risk by preventing incorrect or unintended ingredients from being incorporated. It includes steps to mitigate the hazards identified in the Product Quality Plan. It also ensures uniformity among all batches produced.

Manufacturers must have a Master Manufacturing Protocol for each unique formula and batch size manufactured. The steps of the Master Manufacturing Protocol are documented in a Batch Production Record when they are performed. Master Manufacturing Protocols must be disclosed, upon request, to the Department of Cannabis Control.

The checklist below will help verify that your Master Manufacturing Protocols include the required information. A complete list of requirements can be found in section <u>17215</u> of the regulations.

Checklist for Master Manufacturing Protocol

	Product name
П	Intended cannabinoid concentration

Ingredients/Components

Overall Information

A complete list of each component to be used - This includes all substances used in
the production of a cannabis product, whether it remains in the finished product or not.
This includes, but is not limited to, ingredients and any chemicals or substances used
during extraction or post-processing (ex: ethanol, butane, carbon dioxide, propane etc.)

- □ **Weight or measure of each component to be used** The Master Manufacturing Protocol may include any steps needed to adjust cannabis ingredients to account for variability of cannabinoid content in harvest batches.
- □ **Identity and expected weight or measure of finished product ingredients** This includes all ingredients that will be declared on the labeled ingredients list.

Production Steps

	Instructions for each point, step or stage in the manufacturing process – This
	includes the step to be performed and timeframes, temperatures, equipment settings,
	or other specific parameters. For example, extraction parameters, homogenization
	processes, mixing times, temperature ranges, oven time, target weights or volumes, and
	equipment operating steps.
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Instructions for any actions taken to mitigate risks identified in the Product Quality Plan

□ **Expected Yield** – This value is based on the amount of ingredients or packaging to be used, before accounting for any loss or errors during production. This is also a good place to specify an acceptable range (e.g., minimum and maximum percentage of the expected yield), so there is clarity on when an investigation may be needed to determine the source of unusual excess or loss.

Packaging and Labeling

Description of packaging to be used
Copy of the label (or a reference to the physical location of the label)

□ Expected number of packages and labels to be used – If the cannabis product will leave the manufacturing premises in final form

The Department of Cannabis Control (DCC) licenses and regulates commercial cannabis activity within California. To learn more about the California cannabis market, state licenses or laws, visit <u>cannabis.ca.gov</u>. Email questions to <u>info@cannabis.ca.gov</u> or call 1-844-61-CA-DCC (1-844-612-2322).

